

Osimatab™

Osimertinib Mesylate INN Film Coated Tablet

DESCRIPTION

Osimatab™ is a preparation of Osimertinib Mesylate. Osimertinib is kinase inhibitor of the epidermal growth factor receptor (EGFR), which binds irreversibly to certain mutant forms of EGFR (T790M, L858R, and exon 19 deletion) at approximately 9-fold lower concentrations than wild-type. In cultured cells and animal tumor implantation models, Osimertinib exhibited anti-tumor activity against NSCLC lines harboring EGFR-mutations (T790M/L858R, L858R, T790M/exon 19 deletion, and exon 19 deletion) and, to a lesser extent, wild-type EGFR amplifications. Two pharmacologically-active metabolites (AZ7550 and AZ5104 circulating at approximately 10% of the parent) with similar inhibitory profiles to Osimertinib have been identified in the plasma after oral administration of Osimertinib. AZ7550 showed a similar potency to Osimertinib, while AZ5104 showed greater potency against exon 19 deletion and T790M mutants (approximately 8-fold) and wild-type (approximately 15-fold) EGFR. In vitro, Osimertinib also inhibited the activity of HER2, HER3, HER4, ACK1, and BLK at clinically relevant concentrations.

INDICATIONS

Indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC).

DOSAGE AND ADMINISTRATION

80 mg orally once daily until disease progression or unacceptable toxicity, with or without food.

CONTRAINDICATIONS

None

SIDE EFFECTS

- Diarrhea
- Rash, dry skin
- Nail toxicity

PRECAUTION AND WARNING

- Interstitial Lung Disease (ILD)/Pneumonitis: Occurred in 3.3% of patients. Permanently discontinue Osimertinib in patients diagnosed with ILD/Pneumonitis.
- QTc Interval Prolongation: Monitor electrocardiograms and electrolytes in patients who have a history or predisposition for QTc prolongation, or those who are taking medications that are known to prolong the QTc interval. Withhold then restart at a reduced dose or permanently discontinue Osimertinib.
- Cardiomyopathy: Occurred in 1.4% of patients. Assess left ventricular ejection fraction (LVEF) before treatment and then every 3 months thereafter.

- Embryo-Fetal Toxicity: Osimertinib can cause fetal harm. Advise females of potential risk to the fetus and to use effective contraception during treatment with Osimertinib and for 6 weeks after final dose. Advise males to use effective contraception for 4 months, after the last dose of Osimertinib.

DRUG INTERACTIONS

- Strong CYP3A Inhibitors: Avoid concomitant administration of Osimertinib with strong CYP3A inhibitor including macrolide, antibiotics, antifungals (e.g. Itraconazole), Ritonavir if possible. If no alternative exists, the patient should be closely monitored for signs of toxicity.
- Strong CYP3A Inducers: Avoid concomitant administration of Osimertinib with strong CYP3A inducers (for e.g. Rifampicin, Phenytoin, Carbamazepine) if possible because concomitant use may decrease Osimertinib plasma concentrations.

USE IN PREGNANCY AND LACTATION

There are no available data on Osimertinib use in pregnant women. Administration of Osimertinib to pregnant rats was associated with embryolethality and reduced fetal growth at plasma exposures 1.5 times the exposure at the recommended human dose.

There are no data on the presence of Osimertinib in human milk, the effects of Osimertinib on the breastfed infant or on milk production. Administration to rats during gestation and early lactation was associated with adverse effects, including reduced growth rates and neonatal death.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light & wet place. Keep out of reach of children.

PACKAGING

Osimatab™ 40 FCT: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Osimertinib Mesylate INN equivalent to Osimertinib 40 mg.

Osimatab™ 80 FCT: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Osimertinib Mesylate INN equivalent to Osimertinib 80 mg.

SK+F ONCOLOGY

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM1550 V01